

BARDA INDUSTRY DAY

Contracting for Countermeasures



June 7-9, 2011
San Diego, California

AGENDA

DAY 1

Tuesday, June 7, 2011

Meeting Room 16 A & B

8:30 – 10:00 AM

Plenary Session

Opening Remarks and Welcome

Secretary's Review ~ Five Initiatives ~ New Business Model

Robin A. Robinson, Ph.D.

Deputy Assistant Secretary for Preparedness and Response

Director, Biomedical Advanced Research and Development Authority

U.S. Department of Health and Human Services

Working with the U.S. Government

Barbara Solow, Ph.D.

Vice President of External Development

Emergent BioSolutions, Inc.

AM Break

Meeting Room 17 A

Pandemic Influenza Countermeasures

Moderator: Michael Perdue, Ph.D., Director

BARDA/ Influenza Division

10:20 – 10:50 AM

The Pandemic Influenza Portfolio

Michael Perdue, Ph.D., Director

BARDA/Influenza Division

10:50 – 11:20 AM

Stockpiling Antivirals and Other Countermeasures

Julie Schafer, Project Officer

BARDA/ Influenza Division

11:20 AM – 11:50 AM

Existing Influenza Vaccines and Adjuvants

Vittoria Cioce, Ph.D., Section Chief, Stockpiles

BARDA/ Influenza Division

11:50 AM – 12:15 PM

Stockpiling for Influenza - Discussion

Meeting Room 17 B

Chemical, Biological, Radiological and Nuclear Countermeasures

Moderator: Gary Disbrow, Ph.D., Deputy Director

BARDA/ CBRN Medical Countermeasures Division

10:20 – 11:00 AM

CBRN Advanced Research and Development and Project BioShield (2004 - 2011)

Gerald Kovacs, Ph.D., Director

BARDA/ CBRN Medical Countermeasures Division

11:00 AM – 12:00 PM

Vaccines

Tom Dreier, Ph.D., Program Manager, Anthrax Vaccines

Mike Merchlinsky, Ph.D., Project Manager,

Smallpox Vaccines

BARDA/ CBRN Medical Countermeasures Division

Lunch On Your Own
12:00 – 1:15 PM
(See Directory of Local Restaurants)

1:15 – 1:45 PM

Advanced Development of Novel Influenza Vaccines

Robert Huebner, Ph.D., Deputy Director
 BARDA/ Influenza Division

1:45 – 2:15 PM

Advanced Development of New Influenza Antivirals

Rick Bright, Section Chief, Antiviral Drugs
 BARDA/ Influenza Division

2:15 – 2:45 PM

Advanced Development of Diagnostics and Other Devices

Roxanne Shively, Section Chief, Diagnostics
 BARDA/ Influenza Division

1:15 – 2:15 PM

Therapeutics

Anthrax Programs

Terri Richards, M.S., Project Officer, Antitoxins/Therapeutics

Botulism Programs

Melissa Willis, Ph.D., Project Officer, Antitoxins/Therapeutics
 BARDA/CBRN Medical Countermeasures Division

2:15 – 3:15 PM

Chemical, Radiation and Nuclear MCMs Programs

Ronald Manning, Ph.D., Chief
 CRN Medical Countermeasures
 BARDA/CBRN Medical Countermeasures Division

PM Break

3:00 – 4:00 PM

BARDA's New Influenza Broad Agency Announcement

Matt Lawlor, Project Officer
 BARDA/ Influenza Division

4:00 – 5:00 PM

Q & A Session

Moderator: Michael Perdue, Ph.D., Director
 BARDA/ Influenza Division

3:30 – 4:00 PM

Diagnostics and Biodosimetry Programs

Rodney Wallace, Chief, Diagnostics
 BARDA/CBRN Medical Countermeasures Division

4:00 – 5:00 PM

Broad Spectrum Antimicrobials Programs

Joe Larsen, Ph.D., Chief
 Broad Spectrum Antimicrobials
 BARDA/CBRN Medical Countermeasures Division

DAY 2

Wednesday, June 8, 2011

Meeting Room 16 A & B

Contracting for Countermeasures

*Moderator: Michael Balady, Ph.D., MSPH
 ASPR/Office of Acquisitions Management, Contracts, and Grants*

8:30 – 8:45 AM

Introduction to Contracting

Michael Balady, Ph.D., MSPH, Director
 ASPR/Office of Acquisitions Management, Contracts, and Grants

8:50 – 9:50 AM

How to Respond to an RFP

Andre Early, Section Chief
 ASPR/Office of Acquisitions Management, Contracts, and Grants

AM Break

10:05 – 10:35 AM

Other Transaction Authority

Glynis Fisher, Section Chief and John Ablard, OTA Analyst
ASPR/Office of Acquisitions Management, Contracts, and Grants

10:40 – 11:20 AM

Broad Agency Announcements and Pre-Proposal Conference

Glynis Fisher, Section Chief, Carolyn Keeseman, Contracting Officer
and CBRN and SST Program Officers
ASPR/Office of Acquisitions Management, Contracts, and Grants

11:25 – 11:55 AM

Small Business Administration

Famane Brown, Section Chief
ASPR/Office of Acquisitions Management, Contracts, and Grants

Lunch On Your Own

12:00 – 1:00 PM

(See Directory of Local Restaurants)

1:00 – 1:30 PM

Earned Value Management

Carl Ruggiero, Earned Value Management Specialist
ASPR/Office of Acquisitions Management, Contracts, and Grants

1:35 – 2:20 PM

Technical Evaluation Panel

Brian Goodger, Deputy Director
ASPR/Office of Acquisitions Management, Contracts, and Grants

PM Break

2:35 – 3:05 PM

Decision Gate

Jolinda Summers, Acquisition Project Management Specialist
(Contractor in support of ASPR/AMCG)
ASPR/Office of Acquisitions Management, Contracts, and Grants

***End of Day for Those Not Participating
in Pre-scheduled Individual Meetings***

Meeting Room 8

3:30 – 4:30 PM

Pre-Scheduled Individual Meetings with AMCG Contracting Officers

ASPR/Office of Acquisitions Management, Contracts, and Grants

DAY 3

Thursday, June 9, 2011

Meeting Room 16 A & B

Strategic Science and Technology Innovations

*Moderator: Jonathan Seals Ph.D., Director
BARDA/Strategic Science and Technology Division*

8:30 – 9:00 AM

**Innovative Technologies to Build a More Responsive Countermeasure
Development and Manufacturing Capability**

*Jonathan Seals, Ph.D., Director
BARDA/Strategic Science and Technology Division*

9:00 – 9:30 AM

BARDA Programs to Foster Technological Innovation

*Brian Dattilo, Ph.D., Project Officer
BARDA/Strategic Science and Technology Division*

9:30 – 10:00 AM

An Open Dialogue: Contacting and Communicating with BARDA

*Brian Dattilo, Ph.D., Project Officer
BARDA/Strategic Science and Technology Division*

Division of Manufacturing Facilities and Engineering

*Moderator: Thomas Warf, Director
BARDA/Division of Manufacturing*

10:00 – 11:00 AM

**Introduction to the Division of Manufacturing Facilities and Engineering
And Programmatic Responsibilities**

*Tom Warf, Director
BARDA/Division of Manufacturing Facilities and Engineering*

AM Break

Division of Clinical Studies

*Moderator: Jo Ellen Schweinle, M.D., Senior Program Manager
BARDA/Division of Clinical Studies*

11:15 – 11:30 AM

Introduction to the Division of Clinical Studies

*Jo Ellen Schweinle, M.D., Senior Program Manager
BARDA/Division of Clinical Studies*

11:30 – 11:50 AM

Programmatic Responsibilities

*Corrina Pavetto, M.S., RAC, Program Manager
BARDA/Division of Clinical Studies*

11:50 AM – 12:10 PM

Expertise

*James King, M.D., Senior Program Manager
BARDA/Division of Clinical Studies*

Lunch On Your Own

12:15 – 1:15 PM

(See Directory of Local Restaurants)

Regulatory and Quality Affairs Division & HHS Food and Drug Administration

*Moderator: Debra Yeskey, Pharm.D., Director
BARDA/Regulatory and Quality Affairs Division*

1:15 – 1:45 PM

Introduction to BARDA RQA

*Debra Yeskey, Pharm.D., Director
BARDA/Regulatory and Quality Affairs Division*

1:45 – 2:45 PM

Great Expectations... What FDA Expects In Your Submissions

*Suzanne Sensabaugh, MS, MBA
Senior Regulatory Advisor
BARDA/Regulatory and Quality Affairs Division*

*Cynthia L. Kelley, MS
Senior Advisor for Counterterrorism/Medical Countermeasures
IOD/CBER/FDA/HHS*

*Rosemary Roberts, M.D., FAAP
Director, Office of Counter-Terrorism and Emergency Coordination
CDER/FDA/HHS*

PM Break

3:00 – 4:00 PM

Diagnostic MCM Regulatory Lessons Learned

*Lisa Borek, RAC
Regulatory Affairs Specialist
BARDA/Regulatory and Quality Affairs Division*

*Sally A. Hojvat, Ph.D., MSc
Director, Division of Microbiology Devices
Office of In-vitro Diagnostic Device Evaluation and Safety
CDRH/FDA*

4:00 – 4:30 PM

The Use of MCMs in an Emergency

*Debra Yeskey, Pharm.D., Director
BARDA/Regulatory and Quality Affairs Division*

4:30 – 5:00 PM

Update on FDA's Regulatory Science Initiative

*Alan Liss, Ph.D.
Director, MCMi PHSAT
Office of Counterterrorism and Emerging Threats (OCET)
OCS/OC/FDA/HHS*

Meeting Room 8

DAY 1 – Tuesday, June 7, 2011

1:30 – 4:30 PM

Day 3 – Thursday, June 9, 2011

1:30 – 4:30 PM

Pre-Scheduled BARDA Program Staff Meetings

